

§ 880.5430

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 65 FR 2318, Jan. 14, 2000]

§ 880.5430 Nonelectrically powered fluid injector.

(a) *Identification*. A nonelectrically powered fluid injector is a nonelectrically powered device used by a health care provider to give a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body. It may be used for mass inoculations.

(b) *Classification*. Class II (performance standards).

§ 880.5440 Intravascular administration set.

(a) *Identification*. An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

(b) *Classification*. Class II (special controls). The special control for pharmacy compounding systems within this classification is the FDA guidance document entitled "Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers." Pharmacy compounding systems classified within the intravascular administration set are exempt from the premarket notification procedures in subpart E of this part and subject to the limitations in § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 15798, Mar. 21, 2001]

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§ 880.5450 Patient care reverse isolation chamber.

(a) *Identification*. A patient care reverse isolation chamber is a device consisting of a roomlike enclosure designed to prevent the entry of harmful airborne material. This device protects a patient who is undergoing treatment for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality. The device includes fans and air filters which maintain an atmosphere of clean air at a pressure greater than the air pressure outside the enclosure.

(b) *Classification*. Class II (performance standards).

§ 880.5475 Jet lavage.

(a) *Identification*. A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid. The device consists of the pulsing head, tubing to connect to a container of sterile fluid, and a means of propelling the fluid through the tubing, such as an electric roller pump.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5500 AC-powered patient lift.

(a) *Identification*. An AC-powered lift is an electrically powered device either fixed or mobile, used to lift and transport patients in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and slings to support the patient.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5510 Non-AC-powered patient lift.

(a) *Identification*. A non-AC-powered patient lift is a hydraulic, battery, or mechanically powered device, either